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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/701,335	11/04/2003	Jose Luis Moctezuma de la Barrera	29997/061	4924
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MCCRACKEN & FRANK LLP 200 W. ADAMS STREET SUITE 2150 CHICAGO, IL 60606			EXAMINER KHOLDEBARIN, IMAN K	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 10/05/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/701,335

Applicant(s)

DE LA BARRERA, JOSE LUIS  
MOCTEZUMA

Examiner

I Kenneth Kholdebarin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed June 02, 2007 have been fully considered but they are not persuasive.

2. After further consideration of the applicant's argument, examiner respectfully disagrees. In regards to applicant's remarks on page 6 and 7 in regards of claims 1 and 11 and their dependents, applicant argues that Quaid "does not disclose the step of performing an anatomical survey of the joint and the associated limb".

Examiner would like to further clarify that with respect of Quaid's teaching (herein after REF A) and in response to applications argument that REF A does not teach the survey of the joint, Quaid's discloses that "If desired, other types of sensing devices may be coupled to haptic device 113 or surgical tool 112 to determine other properties of anatomy 114. These properties may be used to determine the type of tissue that is in proximity to haptic device 113. Thus, haptic device 113 may be used to differentiate between hard and soft bones, healthy and diseases tissues, different types of healthy tissues, boundaries of anatomical structures, etc. Based on information received from haptic device 113, the type of the tissue may be automatically determined by CAS system 11 and displayed on display device 30."

Therefore, the examiner maintain previous rejections dated Jan 29, 2007.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-17 are rejected under 35 U.S.C. 102 (e) as being anticipated by Quaid (US 2004/0106916).

Re Claim 10: Quaid discloses a method for registering two dimensional image data to intra-operatively digitized land mars comprising the steps of importing the two dimensional image data (S1 / Fig. 13) for the joint into memory of a surgical navigation system (10) capable of determining the position and orientation of an object within a working volume wherein the surgical navigation system includes a display (30) a central processing unit and storage (all included in computer system (10) [See paragraph 0037]; performing an anatomical survey of the joint and associate limb (step 142 / Fig. 3A) [See paragraph 0061]; digitizing selected landmarks based on the anatomical survey (\$3) [See paragraph 0054]; determining a mechanical axis for the limb based on the digitized landmarks registering the two dimensional image data to the mechanical axis and displaying the registered image data on the display (30) [See paragraph 0045]; guiding a cutting jig into position within the knee joint using the surgical navigation system based on the landmarks [step 148, See paragraph 0067].

Re Claim 11: Quaid disclose the displaying of the position of the cutting jig / surgical device (212) on the display (30) relative to the registered two dimensional image data [See paragraph 0067].

Re Claim 12: Quaid discloses the displaying of a modified image (through the system (10) which includes the display (30) for the image data) based on the two dimensional image data showing a resection of a bone within the joint [See paragraph 0112].

Re Claim 13 and 14: Quaid discloses the method of obtaining two dimensional image data to be obtained pre-operatively and intra- operatively. (Quaid considers monitoring the body part under the surgery) [See paragraph 0004].

Re Claim 15: Quaid discloses the performing an initial kinematics assessment of the joint (step 708 applying block 2504-2506) [See paragraph 0162 and 0152].

Re Claim 16 and 17: Quaid discloses the method of registering the image data to the digitized landmarks and the kinematics assessment [See paragraph 0054 and 0081 ].

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable in view of Quaid (2004/0106916).

Re Claim 1: Quaid discloses a system (10) for registering two dimensional image data to intra-operatively digitized landmarks where a surgical navigation system/modual navigation Of computer (36) system capable of determining a position and an orientation of an object within a working volume, including a central processing unit / processor of computer (36), a display (30) a memory unit and a storage unit / memory and storage of computer 21 [See paragraph 0035] Quaid discloses integrated of the imaging device to the computer surgical system to import the image data [See paragraph 0042].

Further Quaid discloses the system (10) of the navigation surgical device capable of performing an intra-operative anatomical survey of the joint and associated limb to digitize selected landmarks and determine a mechanical axis [See paragraph 0054]

Quaid discloses the system (10) with navigation system to register the two dimensional image • data of patient to the mechanical axis and display (30) the registered two dimensional image data on the display [See Paragraph 0004]

Quaid discloses the system (10) with the help of haptic device can be used to guide the user in removing the diseased bone and guiding a cutting jig into position within the joint based on the landmarks wherein the position and orientation of the cutting jig / (surgical device 112) can be tracked by the surgical navigation system [See Paragraph 0056 and 0057].

Although Quaid fails to specifically disclose four separate circuits within one system, it would

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have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to assist the surgeons in joint

replacement surgery and particularly knee replacement surgery by using a surgical navigation system.

Re Claim 2: Quaid disclose a display (30) of system (10) to displays the position of cutting jig / surgical device (112) on the display relative to the registered two dimensional image data [See Fig. 12, and paragraph 0058].

Although Quaid fails to specifically disclose fourth circuit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of Circuit, in order to display the position of cutting jig iar any relevant surgical device to assist the surgeons in joint replacement to identify the location of operation.

Re Claim 3: Quaid discloses the display of image based on the registered image data showing a resection plane of a bone within the joint. (In orthopedic application with the help ofhaptic device (30)) [See paragraph 0109].

Although Quaid fails to specifically disclose a fourth circuit, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to display an image based on the registered image data showing a resection plane in order tO guide the surgeon in the bone cutting operation, the skill level of the surgeon is less critical.

Re Claim 4: Quaid discloses the image data is obtained intra-operatively (as part of the utilities of system (10)) [See paragraph 0004].

Re Claim 5: Quaid discloses a system with haptic device (113) that performs an initial kinematics assessment of the joint [See paragraph 0053].

Although Quaid fails to specifically disclose a fifth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to perform initial kinematics assessment in order create the input for to coordinate transformation process.or to assist the surgeon to find the coordinate of the joint.

Re Claim 6: Quaid discloses the software module to register the image data to the digitized landmarks, and to the kinematics assessment. Quaid explains that the registration may include any known registration technique, such as image to image or image to physical space [See paragraph 0043].

Although Quaid fails to specifically disclose a third circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one Or different number of circuit, in order to register the image data to the landmarks for a better visualization of the landmark locations on the image displayed intra- operation.

Re Claim 7: Quaid discloses the system (10) to display of digitized landmarks along with the registered two dimensional image data on display (30) [See paragraph 0040].

Although Quaid fails to specifically disclose a fourth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have one system with one or different number of circuit, in order to display the landmarks on the image



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data for a better visualization of the landmark locations on the image displayed intra-operation.

Re Claim 8: Quaid discusses about applying of plane resection to assist the surgeons with varying degrees of skill and experience to be able to perform accurate, repeatable bone resections.

Although Quaid fails to disclose or fairly suggest a fourth circuit to displays a proposed resection plane on the registered two dimensional image data, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display the resection plane on a registered image, in order to clearly define the excision of all or part of a bone and assist the orthopedic surgeons.

Re Claim 9: Quaid discloses that the system (10) via the display (30) is able to displays the varus / valgus data and extension flexion data in display (30) [See paragraph 0113].

Although Quaid fails to specifically disclose a fourth circuit within the system, it would have been obvious to one of ordinary skill in the art at the time the invention was made to display varus/valgus angle, and flexion angle in order to help the user implanting a first implant on a first bone.

### **Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Hunter discloses Six degree of freedom alignment display for medical procedures ; Abovitz discloses System and method for intra-operative haptic planning of a medical procedure; Carson discloses Surgical navigation systems and processes for high tibial osteotomy ; Krause

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discloses Computer-aided orthopedic surgery ; Kande discloses Computer aided surgical plan provision method for orthopedic surgery, involves generating final surgical plan based on generated pre-surgical plan and intra-operative feedback obtained from surgeon; Chader discloses imaging system having interactive medical instruments and methods; Bucholz discloses system for indicating the position of a surgical probe within a head on an image of the head.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F 8 AM- 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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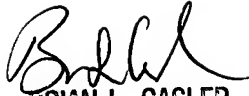
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/Iman Kenneth Kholdebarin/

09/27/2007

  
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